K063343

DEC 13 2006

Section 5: 510(k) Summary

In response to the Safe Medical Devices Act of 1990, the following is a summary of the safety and effectiveness information upon which the substantial equivalence determination is based.

Sponsor/ Manufacturer: Bioptigen, Inc.
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Date Prepared: October 4, 2006

Proposed Class: II

Proprietary Name: Bioptigen Spectral Domain Ophthalmic Imaging System

Common Name: Ophthalmic Imaging Device

Classification Name: Ophthalmoscope, A-C powered

Regulation Number: 21 CFR 886.1570

Product Code: HLI

Predicate Device: Carl Zeiss Meditec Stratus OCT (K033123), Carl Zeiss Humphrey OCT 3 (K012727)

Intended Use: The Bioptigen Spectral Domain Ophthalmic Imaging System is intended to acquire, process, display, and save depth-resolved images of ocular tissue microstructure using Spectral Domain Optical Coherence Tomography. It is primarily intended for the imaging of retinal tissue, but the cornea, sclera, and conjunctiva can also be imaged by changing the focal position. Indications for use include the evaluation of ophthalmic tissue in routine clinical examinations and as an aid in the diagnosis of conditions that affect the optical scattering properties of ocular tissue.

Device Description: The Bioptigen Spectral Domain Ophthalmic Imaging System is a noninvasive imaging device which provides microscopic tomographic sectioning of the retina with $\leq$ 6 microns axial resolution. The Bioptigen System is capable of 20,000 A-Scans/second due to the nature of spectral domain optical coherence tomography.

The Bioptigen Spectral Domain Ophthalmic system is composed of a host computer, engine, and probe. The OCT engine is driven by instrument cards in the computer. The device software will allow a user to create, display, load, and save image files (OCT files).

Summary of non-clinical tests: Conformance to standards including ISO 10942, ISO 15004-1, and ISO 15005-2.2 confirms the safety and performance of the proposed device. Safety analysis concludes that under normal operating conditions the energy exposure to the eye does not exceed the limits for human ocular exposure.

Technological Comparison:

	Zeiss OCT 3	Zeiss StratusOCT	Bioptigen SDOCT Retinal Imaging System
K number	**K012727**	**K033123**	**Not assigned**
Indication for Use	Viewing and axial cross sectional imaging of posterior ocular structures. It is used for in vivo imaging and measurement of the retina, retinal nerve fiber layer and optic disk.	Same- includes RNFL and Macula Normative Database	The Bioptigen Spectral Domain Ophthalmic Imaging System is intended to acquire, process, display, and save depth-resolved images of ocular tissue microstructure using Spectral Domain Optical Coherence Tomography.
Category	**Specification**	**Specification**	**Specification**
Optical power	<= 750 microwatts at cornea	<= 750 microwatts at cornea	<= 750 microwatts at cornea
Longitudinal resolution	20 um in tissue	20 um in tissue	20 um in tissue
Axial resolution	<= 10 um in tissue	<= 10 um in tissue	<= 6 um in tissue[i]
Scanner type	Galvanometric mirror	Galvanometric mirror	Galvonometric mirror pair
Scan patterns available	Line, circle, concentric rings, radial lines	Line, circle, concentric rings, radial lines	Line, circle, concentric rings, radial lines
Scan pixels	Adjustable from 1,024 (axial) x 128 (transverse) to 1,024 (axial) x 768 (transverse)	Adjustable from 1,024 (axial) x 128 (transverse) to 1,024 (axial) x 768 (transverse)	Adjustable from 512 (axial) x 10 (transverse) to 2,048 (axial) x 10,000 (transverse)[ii]
Depth range	2 mm in tissue	2 mm in tissue	2.2 mm in tissue
Scan rate	400 A scans/s	400 A scans/s	20,000 A-scans/s[iii]
Internal fixation	32 x 16 LED dot matrix	32 x 16 LED dot matrix	220 x 200 Color LCD[v]
External fixation	Slit lamp type adjustable blinking LED	Slit lamp type adjustable blinking LED	Slit lamp type adjustable LED
Minimum pupil diameter	3.2 mm	3.2 mm	3 mm
User Features			
Processor	2.4 GHz Pentium IV	2.4 GHz Pentium IV	Dual 3.4 GHz Xeon Processors
Operating system	Windows 2000	Windows 2000	Windows XP
Memory	512 Mb	512 Mb	2 GHz

Summary of clinical tests: Not required

Conclusions from non-clinical tests: Conformance to standards including ISO 10942, ISO 15004-1, and ISO 15005-2.2 confirms the safety and performance of the proposed device for intended use. While there are technological differences in the resolution capabilities, acquisition rate, and internal fixation of the Bioptigen Spectral Domain Ophthalmic Imaging System and the predicate devices, these differences do not present new questions of safety and effectiveness; thus, the devices are considered to be substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 13 2006

Bioptigen, Inc.
c/o Jeffrey D. Rongero
Underwriters Laboratories, Inc.
12 Laboratory Dr.
Research Triangle, NC 27709

Re: K063343
Trade/Device Name: Bioptigen Spectral Domain Ophthalmic Imaging System
Regulation Number: 21 CFR 886.1570
Regulation Name: Ophthalmoscope
Regulatory Class: Class II
Product Code: HLI
Dated: November 27, 2006
Received: November 28, 2006

Dear Mr. Rongero:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

M B Eydelman, MD

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K063343

Device Name: Bioptigen Spectral Domain Ophthalmic Imaging System

Indications For Use: The Bioptigen Spectral Domain Ophthalmic Imaging System is intended to acquire, process, display, and save depth-resolved images of ocular tissue microstructure using Spectral Domain Optical Coherence Tomography. It is primarily intended for the imaging of retinal tissue, but the cornea, sclera, and conjunctiva can also be imaged by changing the focal position. Indications for use include the evaluation of ophthalmic tissue in routine clinical examinations and as an aid in the diagnosis of conditions that affect the optical scattering properties of ocular tissue.

Prescription Use__XX__ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Bruce Drum

(Division Sign-Off)
Division of Ophthalmic Ear, Nose and Throat Devises
510(k) Number K063343